K100485

SL-2010-001

MAR 16 2010

Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

Submitted by:

Susan Lin
Manager, Regulatory Affairs
Ethicon, Inc., a *Johnson & Johnson* Company
Route 22 West, PO Box 151
Somerville, NJ 08876

Name/Classification of Device:

Class II in 21 CFR § 878.3300, Surgical Mesh (OTN)

Trade Name:

GYNECARE TVT EXACT™ Continence System

Predicate Devices:

GYNECARE TVT™ Tension-free Vaginal Tape (K974098), ETHICON, Inc.

Statement of Intended Use:

The GYNECARE TVT EXACT™ Continence System is intended to be used as a pubourethral sling for treatment of female Stress Urinary Incontinence, resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Device Description:

The proposed GYNECARE TVT EXACT™ Continence System consists of the following sterile, single-use components: GYNECARE TVT EXACT™ Continence System Trocar and Trocar Sheath / Implant Assembly.

The GYNECARE TVT EXACT™ Continence System Trocar Sheath / Implant Assembly consists of one piece of PROLENE™Polypropylene Mesh (Implant) approximately 1/2 inch (1.1 cm) wide, 18 inches (45 cm) long , and approximately 0.027 inches (0.7 mm) thick, **which is identical in material and dimensions to the implant of currently marketed GYRECARE TVT™ Device**. The implant is covered by a clear plastic Implant Sheath and held between two white Trocar Sheaths, which are bonded to the Implant and Implant Sheath.

The GYNECARE TVT EXACT™ Continence System Trocar consists of the stainless steel Trocar Shaft and the plastic Trocar Handle. The Trocar Shaft is designed to fit inside the white Trocar Sheaths on the GYNECARE TVT EXACT™ Continence System Implant / Trocar Sheath Assembly, and is used

to position the GYNECARE TVT EXACT™ Continence System Implant in the patient from a vaginal incision up through the abdominal wall.

Summary of Technological Characteristics of New Device to Predicate Devices:

The principle of operation and fundamental scientific technology of the modified device are equivalent to the predicate devices. Both the GYNECARE TVT™ and the GYNECARE TVT EXACT™ function in the same manner - Introducing a retropubic synthetic mesh sling in the patient from a vaginal incision to the abdominal skin that provides mid-urethral support.

Performance Data:

Results of verification testing (such as measurement of key dimensions, Trocar Shaft Yield Force, Peak Torque of Trocar Shaft, Penetration Force, and Lock Failure Force of Trocar Sheath) indicates that modified device meets the established performance requirements.

Conclusions:

Based on the similarities to the predicate device identified in this submission as well as the outcome of design verification we conclude that the modified device is substantially equivalent to the predicate devices under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Susan Lin
Manager, Regulatory Affairs
ETHICON, Inc.
Route 22 West, P0 Box 151
SOMERVILLE NJ 08876

SEP 2 8 2012

Re: K100485
Trade/Device Name: GYNECARE TVT EXACT™ Continence System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: February 18, 2010
Received: February 19, 2010

Dear Ms. Lin:

This letter corrects our substantially equivalent letter of March 16, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100485

Device Name: **GYNECARE TVT EXACT™ Continence System**

Indications for Use:

The GYNECARE TVT EXACT™ Continence System is intended to be used as a pubourethral sling for treatment of female Stress Urinary Incontinence, resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use X . (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K100485